

**REMARKS****I. Claim Status**

Claims 1-59 are currently pending in this application. Claims 6, and 8-59 have been withdrawn from consideration. Claim 1 has been amended. Claims 5 and 7 have been cancelled without prejudice or disclaimer. Upon entry of the present amendment, claims 1-4 will be under examination.

**II. Formalities**

The Examiner has acknowledged and considered the information disclosure statement submitted on June 23, 2006.

The Examiner has also withdrawn the rejection of the claims under 35 U.S.C. §101 in view of the amendments filed in the response of May 24, 2006.

Applicants thank the Examiner for including amended claim 5 for examination in the present case.

**II. Amendments to the claims**

Amended claim 1 recites a particular plurality set of genes "wherein said first group comprises NTT73, CYP7B1 and ABCC3, and wherein said second group comprises BHMT and SAHH." Support for this amendment may be found at least on page 10, lines 10-11 and page 25, lines 4-7 of the specification, in Example 4 and Table IV, and in original claims 5 and 7.

Thus, it is believed that the present amendments are in compliance with 37 C.F.R. §1.116, since claims 5 and 7 have been cancelled, and amended claim 1 incorporates the subject matter of original claims 5 and 7. The amendments are believed to place the claims in condition for allowance. No new matter is added by way of these amendments.

**III. Rejections under 35 U.S.C. §112, first paragraph**

Claims 1-5 and 7 have been rejected as allegedly failing to comply with the written description requirement. The Examiner asserts that although the claims are directed to a plurality of any and all genes that are differentially expressed in kidney cells when exposed to estrogen and/or any other hormone, the specification allegedly only has

limited support for a limited range of genes that appear to be differentially expressed and only in response to a limited number of agents. The Examiner cites to Chern *et al.*, Nephron. 85:258-266 (2000) as being supportive of the difficulty in proving a full set of differentially expressed kidney genes. The Examiner also cites to Kuiper for differential expression patterns for various estrogen receptor subtypes.

In order to expedite prosecution and without conceding the validity of the rejection, claim 1 has been amended to recite particular pluralities of genes: the combination of all of ABCC3, NNTT73, and CYP7B1 as the first group and; and BHMT and SAHH, as the second group. Applicants assert that the amended claim finds adequate written description throughout the specification, and in particular on page 25, lines 4-7, in Example 4 and Table IV.

For all the foregoing reasons, Applicants respectfully submit that the rejections under 35 U.S.C. § 112, paragraph 1, have been fully obviated and should be withdrawn.

**V. Rejections under 35 U.S.C. §102(b)**

Claims 1-5 and 7 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ecker et al. U.S. Patent No. 5,747,253 (“Ecker”). The Examiner describes Ecker as teaching all possible gene fragments from genes expressed in kidney tissue. The Examiner states that the specification describes a “gene” as including gene fragments that may or may not represent a functional domain. The Examiner concludes that since the claims are not limited to isolated genes, that the 8-mer DNA probes of Ecker anticipate the claimed invention.

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. §2131 (8th Ed. Rev. 4, 2006). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984).

Amended claim 1 recites a particular plurality of genes: the combination of all of ABCC3, NNTT73, and CYP7B1 as the first group and; and BHMT and SAHH, as the second group. The 8-mer DNA probes of Ecker do not teach the ABCC3, NNTT73, CYP7B1, BHMT and SAHH genes.

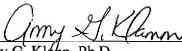
Since Ecker fails to teach all of the elements of the amended claims, Ecker cannot anticipate the present application. Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) under Ecker be withdrawn.

### CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. Applicants reserve the right to pursue the canceled and/or non-elected subject matter in one or more continuation or divisional applications.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

By   
Amy G. Klahn, Ph.D.  
Registration No.: 48,155  
DARBY & DARBY P.C.

Dated: January 29, 2007

P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant